

15992 U.S. PTO
012604

Practitioner's Docket No. U 015009-1

PATENT

Preliminary Classification:

Proposed Class:

Subclass:

NOTE: "All applicants are requested to include a preliminary classification on newly filed patent applications. The preliminary classification, preferably class and subclass designations, should be identified in the upper right-hand corner of the letter of transmittal accompanying the application papers, for example 'Proposed Class 2, subclass 129.'" M.P.E.P. Section 601, 7th ed.

22141 U.S. PTO
10/765002

012604

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Mail Stop Patent Application
Commissioner for Patents
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Alexandria, VA 22313-1450

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00140

PATENT TRADEMARK OFFICE

NEW APPLICATION TRANSMITTAL

Transmitted herewith for filing is the patent application of
Inventor(s):

1. KEENAN MARTIN BORA
2. LAIN-YEN HU
3. SUZANNE ROSS KESTEN
4. HUANYSHU LEI
5. DAVID WINSLOW MORELAND
6. MICHAEL FRANCIS RAFFERTY

WARNING: 37 C.F.R. Section 1.41(a)(1) points out:

"(a) A patent is applied for in the name or names of the actual inventor or inventors.

(1) The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.63, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(I) is filed supplying or changing the name or names of the inventor or inventors."

CERTIFICATION UNDER 37 C.F.R. 1.10*

(Express Mail label number is **mandatory**.)

(Express Mail certification is optional.)

I hereby certify that this correspondence and the documents referred to as attached therein are being deposited with the United States Postal Service on this date January 26, 2004, in an envelope as "Express Mail Post Office to Addressee", mailing Label Number EV 327552045 US, addressed to the Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450

CONNIE YANNOTTI

(type or print name of person mailing paper)

Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

(New Application Transmittal—page 1 of 23) 4-1

EXPRESS MAIL LABEL
NO.: EV 327552045 US

7. TOOD ROBERT RYDER
8. JEFFREY DAVID SCHOLTEN
9. DAVID JUERGEN WUSTROW

For (title): BRANCHED CHAIN AMINO ACID-DEPENDENT AMINOTRANSFERASE
INHIBITORS AND THEIR USE IN THE TREATMENT OF
NEURODEGENERATIVE DISEASES

1. Type of Application

This new application is for a(n)

(check one applicable item below)

- ☐ Original (nonprovisional)
☐ Design
☐ Plant

WARNING: *Do not use this transmittal for a completion in the U.S. of an International Application under 35 U.S.C. 371(c)(4), unless the International Application is being filed as a divisional, continuation or continuation-in-part application.*

WARNING: *Do not use this transmittal for the filing of a provisional application.*

NOTE: If one of the following 3 items apply, then complete and attach ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF A PRIOR U.S. APPLICATION CLAIMED and a NOTIFICATION IN PARENT APPLICATION OF THE FILING OF THIS CONTINUATION APPLICATION.

- ☐ Divisional.
☒ Continuation.
☐ Continuation-in-part (C-I-P).

2. Benefit of Prior U.S. Application(s) (35 U.S.C. Sections 119(e), 120, or 121)

NOTE: *A nonprovisional application may claim an invention disclosed in one or more prior filed copending nonprovisional applications or copending international applications designating the United States of America. In order for a nonprovisional application to claim the benefit of a prior filed copending nonprovisional application or copending international application designating the United States of America, each prior application must name as an inventor at least one inventor named in the later filed nonprovisional application and disclose the named inventor's invention claimed in at least one claim of the later filed nonprovisional application in the manner provided by the first paragraph of 35 U.S.C. Section 112. Each prior application must also be:*

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in Section 1.51(b); or

(iii) Entitled to a filing date as set forth in Section 1.53(b) or Section 1.53(d) and include the basic filing fee set forth in Section 1.16; or

(iv) Entitled to a filing date as set forth in Section 1.53(b) and have paid therein the processing and retention fee set forth in Section 1.21(l) within the time period set forth in Section 1.53(f).

37 C.F.R. Section 1.78(a)(1).

WARNING: *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. §§120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. §§ 120, 121 or 365(c). (35 U.S.C.*

154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. §§ 119, 365(a) or 365(b).) For a C-I-P application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.

WARNING: 37 C.F.R. § 1.78(a)(2) deals with the time in which the claim for the benefit of an earlier filing date must be made and states:

"(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) (in the later-filed international application sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application. The time periods in this paragraph do not apply if the later-filed application is:

- (A) An application for a design patent;
- (B) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or
- (C) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000..

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number."

NOTE: If the new application being transmitted is a divisional, continuation or a continuation-in-part of a parent case, or where the parent case is an International Application which designated the U.S., or benefit of a prior provisional application is claimed, then check the following item and complete and attach **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

- [X] The new application being transmitted claims the benefit of prior U.S. application(s). Enclosed are **ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED**.

3. Papers Enclosed

A. Required for Filing Date under 37 C.F.R. Section 1.53(b) (Regular) or 37 C.F.R. Section 1.153 (Design) Application

149 Pages of Specification
33 Pages of Claims
 Sheets of Drawing

WARNING: *DO NOT submit original drawings. A high quality copy of the drawings should be supplied when filing a patent application. The drawings that are submitted to the Office must be on strong, white, smooth, and non-shiny paper and meet the standards according to Section 1.84. If corrections to the drawings are necessary, they should be made to the original drawing and a high-quality copy of the corrected original drawing then submitted to the Office. Only one copy is required or desired. For comments on proposed then-new 37 C.F.R. 1.84, see Notice of March 9, 1988 . (1990 O.G. 57-62).*

NOTE: *"Identification of drawings. Identifying indicia, if provided, should include the title of the invention, inventor's name and application number , or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin."*

(complete the following, if applicable)

☐ The enclosed drawing(s) are photograph(s).

NOTE: 37 C.F.R. 1.84
"(b) Photographs.

"(1) Black and white. Photographs, including photocopies of photographs, are not ordinarily permitted in utility and design patent applications. The Office will accept photographs in utility and design patent applications, however, if photographs are the only practicable medium for illustrating the claimed invention. For example, photographs, or photomicrographs of: electrophoresis gels, blots (e.g., immunological, western, Southern and northern), auto radiographs, cell cultures (stained and unstained), histological tissue cross sections (stained and unstained), animals, plants, in vivo imaging, thin layer chromatography plates, crystalline structures, and in a design patent application, ornamental effects, are acceptable. If the subject matter of the application admits of illustration by a drawing, the examiner may require a drawing in place of the photograph. The photographs must be of sufficient quality so that all details in the photographs are reproducible in the printed patent.

"(2) Color photographs. Color photographs will be accepted in utility and design patent applications if the conditions for accepting color drawings and black and white photographs have been satisfied. See paragraphs (a)(2) and (b)(1) of this section."

☐ The enclosed drawing(s) are in color. Three (3) sets of color drawings and a "PETITION TO ACCEPT COLOR DRAWING(S)" are attached. 37 C.F.R. §§ 1.84(a)(2) and 1.84(b).

NOTE: 37 C.F.R. 1.84(a)

"(2) Color. On rare occasions color drawings may be necessary as the only practical medium by which to disclose the subject matter sought to be patented in a utility or design patent application or the subject matter of a statutory invention registration. The color drawings must be of sufficient quality such that all details in the drawings are reproducible in black and white in the printed patent. Color drawings are not permitted in international applications (see PCT Rule 11.13), or in an application, or copy thereof, submitted under the Office electronic filing system. The Office will accept color drawings in utility or design patent applications and statutory invention registrations only after granting a petition filed under this paragraph explaining why the color drawings are necessary. Any such petition must include the following:

- (i) The fee set forth in § 1.17(h);
- (ii) Three (3) sets of color drawings;

- (iii) *A black and white photocopy that accurately depicts, to the extent possible, the subject matter shown in the color drawing; and*
- (iv) *An amendment to the specification to insert (unless the specification contains or has been previously amended to contain) the following language as the first paragraph of the brief description of the drawings:*

"The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee."

- ☒ Formal
- ☐ Informal

B. Other Papers Enclosed

- _____ Pages of declaration and power of attorney
- _____ 1 Pages of Abstract
- _____ Other

4. Additional Papers Enclosed

- ☒ Preliminary Amendment
- ☒ Information Disclosure Statement (37 C.F.R. Section 1.98)

WARNING: *In order to ensure consideration of information previously submitted but which has not been considered in the parent application, an applicant must resubmit the information, complying with 37 C.F.R. § 1.97 and 37 C.F.R. § 1.98, in the continuing application filed under 37 C.F.R. § 1.53(b). See § 609B(3), M.P.E.P., 7th Edition, Rev. 1.*

- ☒ Form PTO-1449 (PTO/SB/08A and 08B)
- ☒ Citations
- ☐ Statement of Biological Deposit
- ☐ Submission of "Sequence Listing," computer readable copy and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence.
- ☐ Authorization of Attorney(s) to Accept and Follow Instructions from Representative
- ☐ Special Comments
- ☐ Request for Nonpublication of Application
- ☐ Other

5. Declaration or Oath (including power of attorney)

NOTE: *A newly executed declaration is not required in a continuation or divisional application provided the prior nonprovisional application contained a declaration as required, the application being filed is by all or fewer than all the inventors named in the prior application, there is no new matter in the application being filed, and a copy of the executed declaration filed in the prior application (showing the signature or an indication thereon that it was signed) is submitted. The copy must be accompanied by a statement requesting deletion of the names of person(s) who are not inventors of the application being filed. If the declaration in the prior application was filed under Section 1.47 then a copy of that declaration must be filed accompanied by a copy of the decision granting Section 1.47 status or, if a nonsigning person under Section 1.47 has subsequently joined in a prior application, then a copy of the subsequently executed declaration must be filed. See 37 C.F.R. Section 1.63(d)(1)-(3).*

NOTE: *A declaration filed to complete an application must be executed, identify the specification to which it is directed, identify each inventor by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and the residence, post office address and country of citizenship of each inventor, and state whether the inventor is a sole or joint inventor. 37 C.F.R. Section 1.63(a)(1)-(4).*

NOTE: *The inventorship of a nonprovisional application is that inventorship set forth in the oath or declaration as prescribed by Section 1.62, except as provided for in Section 1.53(d)(4) and Section 1.63(d). If an oath or declaration as*

prescribed by Section 1.63 is not filed during the pendency of a nonprovisional application, the inventorship is that inventorship set forth in the application papers filed pursuant to Section 1.53(b), unless a petition under this paragraph accompanied by the fee set forth in Section 1.17(l) is filed supplying or changing the name or names of the inventor or inventors. 37 C.F.R. Section 1.41(a)(1).

☐ Enclosed

Executed by

(check all applicable boxes)

- ☐ inventor(s).
☐ legal representative of inventor(s). 37 C.F.R. Section 1.42 or 1.43.
☐ joint inventor or person showing a proprietary interest on behalf of inventor who refused to sign or cannot be reached.

☐ This is the petition required by 37 C.F.R. Section 1.47 and the statement required by 37 C.F.R. Section 1.47 is also attached. See item 13 below for fee.

☒ Not Enclosed.

NOTE: *Where the filing is a completion in the U.S. of an International Application, or where the completion of the U.S. application contains subject matter in addition to the International Application, the application may be treated as a continuation or continuation-in-part, as the case may be, utilizing ADDED PAGE FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION CLAIMED.*

☒ Application is made by a person authorized under 37 C.F.R. 1.41 on behalf of *all* the above named inventor(s).

☐ Showing that the filing is authorized.
(not required unless called into question. 37 C.F.R. Section 1.41(d))

6. Inventorship Statement

WARNING: *If the named inventors are each not the inventors of all the claims an explanation, including the ownership of the various claims at the time the last claimed invention was made, should be submitted.*

The inventorship for all the claims in this application are:

☐ The same.

or

- ☐ Not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made,
☐ is submitted.
☐ will be submitted.

7. Language

NOTE: *An application including a signed oath or declaration may be filed in a language other than English. An English translation of the non-English language application and the processing fee of \$130.00 required by 37 C.F.R. Section 1.17(k) is required to be filed with the application, or within such time as may be set by the Office. 37 C.F.R. Section 1.52(d).*

☒ English
☐ Non-English

☐ The attached translation includes a statement that the translation is accurate.
37 C.F.R. Section 1.52(d).

8. Assignment

☒ An assignment of the invention to WARNER-LAMBERT COMPANY LLC

☐ is attached. A separate ☐ "COVER SHEET FOR ASSIGNMENT (DOCUMENT) ACCOMPANYING NEW PATENT APPLICATION" or ☐ FORM PTO 1595 is also attached.

☒ will follow.

☐ has been recorded at Reel _____, Frame _____ on _____

NOTE: "If an assignment is submitted with a new application, send two separate letters-one for the application and one for the assignment" Notice of May 4, 1990 (1114 O.G. 77-78).

WARNING: A newly executed "STATEMENT UNDER 37 C.F.R. Section 3.73(b)" must be filed when a continuation-in-part application is filed **by an assignee**. Notice of April 30, 1993, 1150 O.G. 62-64.

9. Certified Copy

Certified copy(ies) of application(s)

Country	Appln. no.	Filed
Country	Appln. no.	Filed
Country	Appln. no.	Filed

from which priority is claimed

☐ is (are) attached.

☐ will follow.

☐ was filed in parent application _____

NOTE: 37 C.F.R. §1.55. Claim for foreign priority.

"(a) * * *

(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time periods in this paragraph do not apply in an application under 35 U.S.C. 111(a) if the application is:

(A) A design application; or

(B) An application filed before November 29, 2000.

* * * *

(C) *Unless such claim is accepted in accordance with the provisions of this paragraph, any claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) not presented within the time period provided by paragraph (a) of this section is considered to have been waived. If a claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) is presented after the time period provided by paragraph (a) of this section, the claim may be accepted if the claim identifying the prior foreign application by specifying its application number, country (or intellectual property authority), and the day, month, and year of its filing was unintentionally delayed. A petition to accept a delayed claim for priority under 35 U.S.C. 119(a)-(d) or 365(a) must be accompanied by:*

(1) The claim under 35 U.S.C. 119(a)-(d) or 365(a) and this section to the prior foreign application, unless previously submitted;

(2) The surcharge set forth in § 1.17(i); and

(3) A statement that the entire delay between the date the claim was due under paragraph (a)(1) of this section and the date of the claim was filed was intentional. The Commissioner may require additional information where there is a question whether the delay was intentional."

NOTE: 37 C.F.R. § 1.63 Oath or declaration.

"(a) An oath or declaration filed under § 1.51(b)(2) as a part of a nonprovisional application must:

(c) Unless such information is supplied on an application data sheet in accordance with § 1.76, the oath or declaration must also identify:

(2) An foreign application for patent (or inventor's certificate) for which a claim for priority is made pursuant to § 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application number, country, day, month and year of its filing."

The foreign application forming the basis for the claim for priority must be referred to in the oath or declaration. 37 C.F. R. § 1.55(a) and 1.63.

NOTE: *This item is for any foreign priority for which the application being filed directly relates. IF any parent U.S. application or international Application form which this application claims benefit under 35 U.S.C. § 120 is itself entitled to priority from a prior foreign application, then complete item 18 on the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED.*

10. **Fee Calculation** (37 C.F.R. Section 1.16)

A. ☒ Regular application

CLAIMS AS FILED					
Claims	Number Filed	Basic Fee Allowance	Number Extra	Rate	Basic Fee 37 C.F.R. Section 1.16(a) \$770.00
Total Claims (37 C.F.R. Section 1.16(c))	22	-20 =	x 14	\$ 18.00	36.00
Independent Claims (37 C.F.R. Section 1.16(b))	3	- 3 =	x 5	\$ 86.00	
Multiple Dependent Claim(s), if any (37 C.F.R. Section 1.16(d))				\$290.00	

- ☐ Amendment canceling extra claims is enclosed or above.
☐ Amendment deleting multiple-dependencies is enclosed.
☐ Fee for extra claims is not being paid at this time.

NOTE: *If the fees for extra claims are not paid on filing they must be paid or the claims canceled by amendment, prior to the expiration of the time period set for response by the Patent and Trademark Office in any notice of fee deficiency. 37 C.F.R. Section 1.16(d).*

Filing Fee Calculation \$ 806.00

B. ☐ Design application
(\$340.00--37 C.F.R. Section 1.16(f))

Filing Fee Calculation \$ _____

C. ☐ Plant application
(\$530.00--37 C.F.R. Section 1.16(g))

Filing Fee Calculation \$ _____

11. Small Entity Statement(s)

- [] Statement(s) or Written Assertion(s) that this is a filing by a small entity under 37 C.F.R. Section 1.9 and 1.27 is (are) attached.
- [] Applicant hereby asserts small entity status by paying the small entity filing fee.

NOTE: 37 C.F.R. § 1.27(c) deals with the assertion of small entity status; whether by a written specific declaration thereof or by payment as a small entity of the basic filing fee or the fee for the entry into the national phase and states:

"(c) Assertion of small entity status. Any party (person, small business concern or nonprofit organization) should make a determination, pursuant to paragraph (f) of this section, of entitlement to be accorded small entity status based on the definitions set forth in paragraph (a) of this section, and must, in order to establish small entity status for the purpose of paying small entity fees, actually make an assertion of entitlement to small entity status, in the manner set forth in paragraphs (c)(1) or (c)(3) of this section, in the application patent in which such small entity fees are to be paid.

- (1) *Assertion by writing. Small entity status may be established by a written assertion of entitlement to small entity status. A written assertion must:*

- (i) *Be clearly identifiable;*
- (ii) *Be signed (see paragraph (c)(20) of this section); and*
- (iii) *Convey the concept of entitlement to small entity status, such as by stating that applicant is a small entity, or that small entity status is entitled to be asserted for the application or patent. While no specific words or wording are required to assert small entity status, the intent to assert small entity status must be clearly indicated in order to comply with the assertion requirement.*

- (2) *Parties who can sign and file the written assertion. The written assertion can be signed by:*

- (i) *One of the parties identified in § 1.33(b) (e.g., an attorney or agent registered with the Office), § 3.73(b) of this chapter notwithstanding, who can also file the written assertion;*
- (ii) *At least one of the individuals identified as an inventor (even though a § 1.63 executed oath or declaration has not been submitted), notwithstanding § 1.33(b)(4), who can also file the written assertion pursuant to the exception under § 1.33(b) of this part; or*
- (iii) *An assignee of an undivided part interest, notwithstanding §§ 1.33(b)(3) and 3.73(b) of this chapter, but the partial assignee cannot file the assertion without resort to a party identified under § 1.33(b) of this part.*

(3) *Assertion by payment of the small entity basic filing or basic national fee. The payment, by any party, of the exact amount of one of the small entity basic filing fees set forth in §§ 1.16(a), (f), (g), (h), or (k), or one of the small entity basic national fees set forth in §§ 1.492(a)(1), (a)(2), (a)(3), (a)(4), or (a)(5), will be treated as a written assertion of entitlement to small entity status even if the type of basic filing or basic national fee is inadvertently selected in error.*

(i) *If the Office accords small entity status based on payment of a small entity basic filing or basic national fee under paragraph (c)(3) of this section that is not applicable to that application, any balance of the small entity fee that is applicable to that application will be due along with the appropriate surcharge set forth in § 1.16(e), or § 1.16(l).*

(ii) *The payment of any small entity fee other than those set forth in paragraph (c)(3) of this section (whether in the exact fee amount or not) will not be treated as a written assertion of entitlement to small entity status and will not be sufficient to establish small entity status in an application or a patent."*

WARNING: 37 C.F.R. § 1.27(c)(4): "Assertion required in related, continuing, and reissue applications. Status as a small entity must be specifically established by an assertion in each related, continuing and reissue application in which status is appropriate and desired. Status as a small entity in one application or patent does not affect the status of any other application or patent, regardless of the relationship of the applications or patents. The refiling of an application under § 1.53 as a continuation, divisional, or continuation-in-part application (including a continued prosecution application under § 1.53(d)), or the filing of a reissue application, requires a new assertion as to continued entitlement to small entity status for the continuing or reissue application."

WARNING: "Small entity status must not be established when the person or persons signing the . . . statement can unequivocally make the required self-certification." M.P.E.P. Section 509.03, 6th ed., rev. 2, July 1996 (emphasis added).

(complete the following, if applicable)

☐ Status as a small entity was claimed in prior application _____, filed on _____ from which benefit is being claimed for this application under:

35 U.S.C. Section	<input type="checkbox"/>	119(e) - provisional,
	<input type="checkbox"/>	120 - continuation,
	<input type="checkbox"/>	121- divisional,
	<input type="checkbox"/>	365(c) - PCT,

and which status as a small entity is still proper and desired.

☐ A copy of the statement or written assertion in the prior application is included.

Filing Fee Calculation (50% of A, B or C above) \$ _____

NOTE: A refund based on establishment of small entity status, of a portion of fees timely paid in full prior to establishing status as a small entity may only be obtained if an assertion under § 1.27(c) and a request for a refund of the excess amount are filed within three months of the date of the timely payment of the full fee. The three-month time period is not extendable under § 1.136. 37 C.F.R. § 1.28(a).

12. Request for International-Type Search (37 C.F.R. Section 1.104(d))

(complete, if applicable)

- ☐ Please prepare an international-type search report for this application at the time when national examination on the merits takes place.

13. Fee Payment Being Made at This Time

- ☒ Not Enclosed

- ☒ No filing fee is to be paid at this time and any and all prior fee authorizations are revoked.
(This and the surcharge required by 37 C.F.R. Section 1.16(e) can be paid subsequently.)

- ☐ Enclosed

☐ Filing fee \$ _____

☐ Recording assignment
(\$40.00; 37 C.F.R. Section 1.21(h))
(See attached "COVER SHEET FOR
ASSIGNMENT ACCOMPANYING NEW
APPLICATION.") \$ _____

☐ Petition and fee for filing by other
than all the inventors or person
on behalf of the inventor where
inventor refused to sign or cannot
be reached
(\$130.00; 37 C.F.R. Sections 1.47 and 1.17(l)) \$ _____

☐ For processing an application with a
specification in a non-English language
(\$130.00; 37 C.F.R. Sections 1.52(d) and 1.17(k)) \$ _____

☐ Processing and retention fee
(\$130.00; 37 C.F.R. Sections 1.53(d) and 1.21(l)) \$ _____

☐ Fee for international-type search report
(\$40.00; 37 C.F.R. Section 1.21(e)) \$ _____

NOTE: 37 C.F.R. Section 1.21(l) establishes a fee for processing and retaining any application that is abandoned for failing to complete the application pursuant to 37 C.F.R. Section 1.53(f) and this, as well as the changes to 37 C.F.R. Section 1.53 and 1.78(a)(1), indicate that in order to obtain the benefit of a prior U.S. application, either the basic filing fee must be paid, or the processing and retention fee of Section 1.21(l) must be paid, within 1 year from notification under Section 53(f).

Total Fees Enclosed \$ _____

14. Method of Payment of Fees

- ☐ Check in the amount of \$_____.
- ☐ Charge Account No. 12-0425 in the amount of \$_____.
A duplicate of this transmittal is attached.

15. Authorization to Charge Additional Fees

WARNING: *If no fees are to be paid on filing, the following items should not be completed.*

WARNING: *Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges, if extra claim charges are authorized.*

- ☐ The Commissioner is hereby authorized to charge the following additional fees by this paper and during the entire pendency of this application to Account No._____.
- ☐ 37 C.F.R. Section 1.16(a), (f) or (g) (filing fees)
- ☐ 37 C.F.R. Section 1.16(b), (c) and (d) (presentation of extra claims)

NOTE: *Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims canceled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. Section 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

- ☐ 37 C.F.R. Section 1.16(e) (surcharge for filing the basic filing fee and/or declaration on a date later than the filing date of the application)
- ☐ 37 C.F.R. Section 1.17(a)(1)-(5) (extension fees pursuant to Section 1.136(a).
- ☐ 37 C.F.R. Section 1.17 (application processing fees)

NOTE: *"A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under Section 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in Section 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. Section 1.136(a)(3).*

NOTE: *Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application **only after the mailing of the notice of allowance**. Accordingly, general authorizations to pay fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL-85B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b). Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.*

NOTE: 37 C.F.R. Section 1.28(b) requires "Notification of any change in status resulting in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying, . . . issue fee." From the wording of 37 C.F.R. Section 1.28(b), (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity.

16. Instructions as to Overpayment

NOTE: "... Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. Section 1.26(a).

☐ Credit Account No. _____.

☐ Refund

Reg. No. 31,053

Tel. No.: (212)708-1915

Customer No.: 00140



SIGNATURE OF PRACTITIONER

JOHN RICHARDS

(type or print name of practitioner)

LADAS & PARRY

P/O. Address

26 WEST 61ST STREET

NEW YORK, NEW YORK 10023

☒ **Incorporation by reference of added pages**

(check the following item if the application in this transmittal claims the benefit of prior U.S. application(s) (including an international application entering the U.S. stage as a continuation, divisional or C-I-P application) and complete and attach the ADDED PAGES FOR NEW APPLICATION TRANSMITTAL WHERE BENEFIT OF PRIOR U.S. APPLICATION(S) CLAIMED)

☒ **Plus Added Pages for New Application Transmittal Where Benefit of Prior U.S. Application(s) Claimed**

Number of pages added 8

☐ **Plus added pages deleting names of inventor(s) named on prior application(s) who is/are no longer inventor(s) of the subject matter claimed in this application.**

Number of pages added _____

☐ **Statement Where No Further Pages Added**

(if no further pages form a part of this Transmittal, then end this Transmittal with this page and check the following item)

☐ **This transmittal ends with this page.**

**ADDED PAGES FOR APPLICATION TRANSMITTAL WHERE BENEFIT OF
PRIOR U.S. APPLICATION(S) CLAIMED**

NOTE: See 37 CFR 1.78.

17. Relate Back

WARNING: *If an application claims the benefit of the filing date of an earlier filed application under 35 U.S.C. 120, 121 or 365(c), the 20-year term of that application will be based upon the filing date of the earliest U.S. application that the application makes reference to under 35 U.S.C. 120, 121 or 365(c). (35 U.S.C. 154(a)(2) does not take into account, for the determination of the patent term, any application on which priority is claimed under 35 U.S.C. 119, 365(a) or 365(b).) For a c-i-p application, applicant should review whether any claim in the patent that will issue is supported by an earlier application and, if not, the applicant should consider canceling the reference to the earlier filed application. The term of a patent is not based on a claim-by-claim approach. See Notice of April 14, 1995, 60 Fed. Reg. 20,195, at 20,205.*

(complete the following, if applicable)

[X] A separate Preliminary Amendment amends the specification by inserting, before the first line, the following paragraph:

A. 35 U.S.C. 119(e)

NOTE: 37 C.F.R. § 1.78(a)(4) and (5):

"(4) A nonprovisional application, other than for a design patent, or an international application designating the United States of America may claim an invention disclosed in one or more prior-filed provisional applications. In order for an application to claim the benefit of one or more prior-filed provisional applications, each prior-filed provisional application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed provisional application must be entitled to a filing date as set forth in § 1.53(c), and the basic filing fee set forth in § 1.16(k) must be paid within the time period set forth in § 1.53(g).

"(5)(i) Any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed provisional applications must contain or be amended to contain a reference to each such prior-filed provisional application, identifying it by the provisional application number (consisting of series code and serial number).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed provisional application. IF the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national state commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed provisional application. These time periods are not extendable. Except as provided in paragraph (a)(6) of this section, the failure to timely submit the reference is considered a waiver of any benefit under 35 U.S.C. 119(e) to such prior-filed provisional application. The time periods in this paragraph do not apply if the later-filed application is:

(A) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(B) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title."

☐ "This application claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____/_____
_____/_____
_____/_____

and incorporates the same by reference."

WARNING: 37 C.F.R. § 1.78(5)(iv): "(iv) If the prior-filed provisional application was filed in a language other than English and an English-language translation of the prior-filed provisional application and a statement that the translation is accurate were not previously filed in the prior-filed provisional application or the later-filed nonprovisional application, applicant will be notified and given a period of time within which to file an English-language translation of the non-English-language prior-filed provisional application and a statement that the translation is accurate. In a pending nonprovisional application failure to timely reply to such a notice will result in abandonment of the application."

Language of Prior Filed Provisional Application

(Supply information for each provisional the benefit of which is being claimed)

The above identified prior filed provisional application whose benefit is being claimed

☐ was filed in the English language,

☐ was filed in a language other than English and an English translation along with a statement that the translation is accurate was filed in the provisional application, or

☐ was filed in language other than English and an English translation along with a statement that the translation is accurate is filed herewith.

B. 35 U.S.C. 120, 121 and 365(c)

WARNING: The applicable provisions for the time and manner of claiming the benefit of a prior U. S. application filing date are set forth in 37 C.F.R. § 1.78(a)(1) and (2) as follows.:

"(a)(1) A nonprovisional application or international application designating the United States of America may claim an invention disclosed in one or more prior-filed copending nonprovisional applications or international applications designating the United States of America. In order for an application to claim the benefit of a prior-filed copending nonprovisional application or international application designating the United States of America, each prior-filed application must name as an inventor at least one inventor named in the later-filed application and disclose the named inventor's invention claimed in at least one claim of the later-filed application in the manner provided by the first paragraph of 35 U.S.C. 112. In addition, each prior-filed application must be:

(i) An international application entitled to a filing date in accordance with PCT Article 11 and designating the United States of America; or

(ii) Complete as set forth in § 1.51(b); or

(iii) Entitled to a filing date as set forth in § 1.53(b) or § 1.53(d) and include the basic filing fee set forth in § 1.16; or

(iv) Entitled to a filing date as set forth in § 1.53(b) and have paid therein the processing and retention fee set forth in § 1.21(l) within the time period set forth in § 1.53(f).

(2)(i) Except for a continued prosecution application filed under § 1.53(d), any nonprovisional application or international application designating the United States of America claiming the benefit of one or more prior-filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain a reference to each such prior-filed application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross references to other related applications may be made when appropriate (see § 1.14).

(ii) This reference must be submitted during the pendency of the later-filed application. If the later-filed application is an application filed under 35 U.S.C. 111(a), this reference must also be submitted within the later of four months from the actual filing date of the later-filed application or sixteen months from the filing date of the prior-filed application. If the later-filed application is a nonprovisional application which entered the national stage from an international application after compliance with 35 U.S.C. 371, this reference must also be submitted within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) in the later-filed international application or sixteen months from the filing date of the prior-filed application. These time periods are not extendable. Except as provided in paragraph (a)(3) of this section, the failure to timely submit the reference required by 35 U.S.C. 120 and paragraph (a)(2)(i) of this section is considered a waiver of any benefit under 35 U.S.C. 120, 121, or 365(c) to such prior-filed application. The time periods in this paragraph do not apply of the later-filed application is:

(A) An application for a design patent;

(B) An application filed under 35 U.S.C. 111(a) before November 29, 2000; or

(C) A nonprovisional application which entered the national stage after compliance with 35 U.S.C. 371 from an international application filed under 35 U.S.C. 363 before November 29, 2000.

(iii) If the later-filed application is a nonprovisional application, the reference required by this paragraph must be included in an application data sheet (§ 1.76), or the specification must contain or be amended to contain such reference in the first sentence following the title.

(iv) The request for a continued prosecution application under § 1.53(d) is the specific reference required by 35 U.S.C. 120 to the prior-filed application. The identification of an application by application number under this section is the identification of every application assigned that application number necessary for a specific reference required by 35 U.S.C. 120 to every such application assigned that application number."

☒ "This application is a

☒ continuation

☐ continuation-in-part

☐ divisional

of copending

☒ application number 10/381,068 deposited on March 19, 2003

☒ which is

☒ International Application PCT/US01/25892 filed on AUGUST 17, 2001 ,

which designated the U.S.,

claims the benefit thereof and incorporates the same by reference."

NOTE: The proper reference to a prior filed PCT application that entered the U.S. national phase is the U.S. serial number and the filing date of the PCT application that designated the U.S.

NOTE: (1) Where the application being transmitted adds subject matter to the International Application, then the filing can be as a continuation-in-part or (2) if it is desired to do so for other reasons then the filing can be as a continuation.

☐ "The nonprovisional application designated above, namely application _____/_____, filed _____, claims the benefit of U.S. Provisional Application(s) No(s).:

APPLICATION NO(S).:

FILING DATE

_____/_____
_____/_____
_____/_____

and incorporates the same by reference"

C. Publication of International Application-Provisional Application

NOTE: 35 U.S.C. 154 Contents and term of patent; provisional rights

(d)(4) REQUIREMENTS FOR INTERNATIONAL APPLICATIONS—

(A) *EFFECTIVE DATE*—The right under paragraph (1) to obtain a reasonable royalty based upon the publication under the treaty defined in section 351(a) of an international application designating the United States shall commence on the date on which the Patent and Trademark Office receives a copy of the publication under the treaty of the international application, or, if the publication under the treaty of the international application is in a language other than English, on the date on which the Patent and Trademark Office receives a translation of the international application in the English language.

The international application corresponding to the instant application

☒ was
☐ was not

published under PCT Article 21(2) in the English language.

☐ An English translation of the international application is attached.

18. Relate Back—35 U.S.C. 119 Priority Claim for Prior Application

NOTE: 37 C.F.R. § 1.55 Claim for foreign priority.

"(a) An applicant in a nonprovisional application may claim the benefit of the filing date of one or more prior foreign applications under the conditions specified in 35 U.S.C. 119(a) through (d) and (f), 172, and 365(a) and (b).

(1)(i) In an original application filed under 35 U.S.C. 111(a), the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. This time period is not extendable. The claim must identify the foreign application for which priority is claimed, as well as any foreign application for the same subject matter and having a filing date before that of the application for which priority is claimed, by specifying the application number, country (or intellectual property authority), day, month, and year of its filing. The time period in this paragraph does not apply to an application for a design patent.

(ii) In an application that entered the national stage from an international application after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and the Regulations under the PCT."

(2) The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) or PCT Rule 17 must, in any event, be filed before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by the processing fee set forth in § 1.17(i), but the patent will not include the priority claim unless corrected by a certificate of correction under 35 U.S.C. 255 and § 1.323.

The prior U.S. application(s), including any prior International Application designating the U.S., identified above in item 17B, in turn itself claim(s) foreign priority(ies) as follows:

Country	Appln. no.	Filed
---------	------------	-------

Country	Appln. no.	Filed
---------	------------	-------

The certified copy(ies) has (have)

☐ been filed on _____, in prior U. S. national (not PCT) application
_____, which was filed on _____.

☐ is (are) attached.

☐ will follow.

WARNING: *The certified copy of the priority application that may have been communicated to the PTO by the International Bureau may not be relied on without any need to file a certified copy of the priority application in the continuing application. This is so because the certified copy of the priority application communicated by the International Bureau is placed in a folder and is not assigned a U.S. serial number unless the national stage is entered. Such folders are disposed of if the national stage is not entered. Therefore, such certified copies may not be available if needed later in the prosecution of a continuing application. An alternative would be to physically remove the priority documents from the folders and transfer them to the continuing application. The resources required to request transfer, retrieve the folders, make suitable record notations, transfer the certified copies, enter and make a record of such copies in the Continuing Application are substantial. Accordingly, the priority documents in folders of international applications that have not entered the national stage may not be relied on. Notice of April 28, 1987 (1079 O.G. 32 to 46).*

19. Maintenance of Copendency of Prior Application

NOTE: The PTO finds it useful if a copy of the petition filed in the prior application extending the term for response is filed with the papers constituting the filing of the continuation application. Notice of November 5, 1985 (1060 O.G. 27).

A. ☒ Extension of time in prior application

☒ A petition and fee extends the term in the pending **prior** application until JANUARY 26, 2004.

☒ A **copy** of the petition filed in prior application is attached.

B. ☐ Conditional Petition for Extension of Time in Prior Application

☐ A conditional petition for extension of time is being filed in the pending **prior** application.

☐ A **copy** of the conditional petition filed in the prior application is attached.

C. ☐ No extension is necessary in Prior Application

☐ Issue Fee paid _____

20. Further Inventorship Statement Where Benefit of Prior Application(s) Claimed

(complete applicable item (a), (b) and/or (c) below)

(a) ☐ This application discloses and claims only subject matter disclosed in the prior application whose particulars are set out above and the inventor(s) in this application are

☐ the same.

☐ less than those named in the prior application. It is requested that the following inventor(s) identified for the prior application be deleted:

(type name(s) of inventor(s) to be deleted)

(b) ☐ This application discloses and claims additional disclosure and a new declaration or oath is being filed. With respect to the prior application, the inventor(s) in this application are

☐ the same.

☐ the following additional inventor(s) have been added:

(type name(s) of inventor(s) to be added)

(c) ☐ The inventorship for all the claims in this application are

☐ the same.

☐ not the same. An explanation, including the ownership of the various claims at the time the last claimed invention was made

☐ is submitted.

☐ will be submitted.

21. Abandonment of Prior Application *(if applicable)*

☐ Please abandon the prior application at a time while the prior application is pending, or when the petition for extension of time or to revive in that application is granted, and when this application is granted a filing date, so as to make this application copending with said prior application.

NOTE: According to the Notice of May 13, 1983 (103, TMOG 6-7), the filing of a continuation or continuation-in-part application is a proper response with respect to a petition for extension of time or a petition to revive and should include the express abandonment of the prior application conditioned upon the granting of the petition and the granting of a filing date to the continuing application.

22. Petition for Suspension of Prosecution for the Time Necessary to File an Amendment

WARNING: *"The claims of a new application may be finally rejected in the first Office action in those situations where (1) the new application is a continuing application of, or a substitute for, an earlier application, and (2) all the claims of the new application (a) are drawn to the same invention claimed in the earlier application, and (b) would have been properly finally rejected on the grounds of art of record in the next Office action if they had been entered in the earlier application."* MPEP, § 706.07(b).

NOTE: *Where it is possible that the claims on file will give rise to a first action final for this continuation application and for some reason an amendment cannot be filed promptly (e.g., experimental data is being gathered) it may be desirable to file a petition for suspension of prosecution for the time necessary.*

(check the next item, if applicable)

- ☐ There is provided herewith a Petition To Suspend Prosecution for the Time Necessary to File An Amendment (New Application Filed Concurrently)

23. NOTIFICATION IN PARENT APPLICATION OF THIS FILING

- ☐ A notification of the filing of this
(check one of the following)

☐ continuation

☐ continuation-in-part

☐ divisional

is being filed in the parent application, from which this application claims priority under 35 U.S.C. § 120.

IN THE UNITED STATES ELECTED OFFICE (EO/US)

PCT/US01/25892 17 AUGUST 2001 19 SEPTEMBER 2000
INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PRIORITY DATE CLAIMED
BRANCHED CHAIN AMINO ACID-DEPENDENT AMINOTRANSFERASE INHIBITORS
AND THEIR USE IN THE TREATMENT OF NEURODEGENERATIVE DISEASES
TITLE OF INVENTION
KEENAN MARTIN BORA; LAIN-YEN HU; SUZANNE ROSS KESTEN; HUANYSHU LEI;
DAVID WINSLOW MORELAND, MICHAEL FRANCIS RAFFERTY; TODD ROBERT RYDER
JEFFREY DAVID SCHOLTEN; DAVID JUERGEN WUSTROW
APPLICANT(S)

Mail Stop PCT
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

ATTENTION: EO/US

COMPLETION OF FILING REQUIREMENTS
FOR INTERNATIONAL APPLICATION ENTERING U.S. NATIONAL STAGE
IN U.S. ELECTED OFFICE (EO/US) UNDER 35 U.S.C. § 371

(check and complete the applicable item, if applicable)

- [X] This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. § 1.495 (FORM PCT/DO/EO/905).
[X] A copy of FORM PCT/DO/EO/905 accompanies this response.

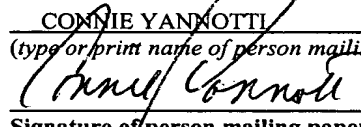
CERTIFICATION UNDER 37 C.F.R. 1.10*

(Express Mail label number is mandatory.)

(Express Mail certification is optional.)

I hereby certify that this Completion of Filing Requirements and the papers indicated as being transmitted therewith are being deposited with the United States Postal Service on this date January 26, 2004, in an envelope as "Express Mail Post Office to Addressee," Mailing Label Number EV327552059US, addressed to the: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450.

CONNIE YANNOTTI
(type or print name of person mailing paper)


Signature of person mailing paper

WARNING: Certificate of mailing (first class) or facsimile transmission procedures of 37 C.F.R. 1.8 cannot be used to obtain a date of mailing or transmission for this correspondence.

***WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. 1.10(b).
"Since the filing of correspondence under § 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable care, requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

WARNING: Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 30 months from the priority date the application is still considered to be in the international state and if mailing procedures are utilized to obtain a date the express mail procedure of 37 C.F.R. § 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 C.F.R. § 108(2)(xi).

NOTE: Documents and fees must be clearly identified as a submission to enter the national stage under 35 U.S.C. § 371. Otherwise, the submission will be considered as being made under 35 U.S.C. § 111. 37 C.F.R. § 1.495(g).

DECLARATION OR OATH

NOTE: 37 C.F.R. § 1.495(c): "If applicant complies with paragraph (b) of this section before expiration of thirty months from the priority date but omits . . . the oath or declaration of the inventor (35 U.S.C. 371(c)(4) and § 1.497), if a declaration of inventorship in compliance with § 1.497 has not been previously submitted in the international application under PCT Rule 4.17 (iv) within the time limits provided for in PCT Rule 26ter.1, applicant will be so notified and given a period of time within which to file the . . . oath or declaration in order to prevent abandonment of the application The payment of the surcharge set forth in § 1.492(e) is required for acceptance of the oath or declaration of the inventor later than the expiration of **thirty** months after the priority date."

I. (a) ☒ No original declaration or oath was filed.

OR

(b) ☐ The declaration or oath that was filed was determined to be defective. A new original oath or declaration is attached.

NOTE: For surcharge fee for filing declaration after filing date complete item IV(3)

NOTE: **NOTE:** Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are:

- (A) application number (consisting of the series code and the serial number, e.g., 08/123,456);
- (B) serial number and filing date;
- (C) attorney docket number which was on the specification as filed;
- (D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or
- (E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration.

M.P.E.P. § 602, 8th ed.

NOTE: Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 C.F.R. § 1.10(c).

NOTE: See 37 C.F.R. § 1.41(a).

(complete as applicable)

Attached is a

- (a) ☐ Statement by practitioner that papers attached to declaration are a copy of those filed in PTO to get a filing date
- (b) ☐ Statement that substitute specification contains no new matter.
- (c) ☐ Preliminary Amendment
- (d) ☐ Submission of "Sequence Listing," computer readable copy, and/or amendment pertaining thereto for biotechnology invention containing nucleotide and/or amino acid sequence

**TRANSMITTAL OF ENGLISH TRANSLATION
OF NON-ENGLISH LANGUAGE PAPERS**

- II.** ☐ Submitted herewith is an English translation of the non-English language international application papers as originally filed. It is requested that this translation be used as the copy for examination purposes in the PTO. (See 37 C.F.R. 1.495(c))

NOTE: For fee for processing a non-English application, complete item IV(4).

NOTE: A non-English oath or declaration in the form provided or approved by the PTO need not be translated. 37 C.F.R. § 1.69(b).

FEES

III.

NOTE: See 37 C.F.R. § 1.28(a).

1. Fees for claims

- ☐ each independent claim in excess of 3
(37 C.F.R. § 1.492(b))—\$86.00; small entity—\$43.00 \$ _____
- ☐ each claim in excess of 20
(37 C.F.R. § 1.492(c))—\$18.00; small entity—\$9.00 \$ _____
- ☐ multiple dependent claims(s)
(37 C.F.R. § 1.492(d))—\$290.00; small entity—\$145.00 \$ _____

2. Surcharge fees
☐ surcharge set forth in 37 C.F.R. § 1.492(e) for accepting the declaration later than 30 months after the priority date in filing an application in the U.S. as a designated office—\$130.00; small entity—\$65.00 \$ _____

NOTE: The processing fee in the next item 3 below is not subject to a reduction for small entity status.

3. ☒ processing fee set forth in 37 C.F.R. § 1.492(f) for acceptance of an English translation later than 30 months after the priority date—\$130.00 \$ 130.00

Total Fees \$ 130.00

SMALL ENTITY STATUS

- IV. a. ☐ A Statement or Written Assertion that this filing is by a small entity

NOTE: See 37 C.F.R. § 1.28(a).

(check and complete applicable items)

- ☐ is attached.
☐ was filed on _____.
☐ was made by paying the basic national fee as a small entity.

- b. ☐ A separate refund request accompanies this paper.

EXTENSION OF TIME

(complete (a) or (b), as applicable)

V.

The proceedings herein are for a patent application. Accordingly, the provisions of 37 C.F.R. § 1.136(a) apply.

- (a) ☒ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below:

Extension (months)	Fee for other than small entity	Fee for small entity
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 420.00	\$ 210.00
<input type="checkbox"/> three months	\$ 950.00	\$ 475.00
<input checked="" type="checkbox"/> four months	\$ 1,480.00	\$ 740.00

Fee: \$ 1,480.00

If an additional extension of time is required, please consider this a petition therefor.

(check and complete the next item, if applicable)

- ☐ An extension for _____ months has already been secured. The fee paid therefor of \$ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ _____

or

- (b) ☐ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

TOTAL FEE DUE

VI.

The total fee due is:

Completion fee(s)	\$ 130.00
Extension fee (if any)	\$ 1,480.00
TOTAL FEE DUE	\$ 1,610.00

PAYMENT OF FEES

VII.

- ☒ Enclosed is a check in the amount of \$ 1,610.00
☐ Charge Account No. 12-0425 in the amount of \$ _____
☐ A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 C.F.R. § 1.22(b).

AUTHORIZATION TO CHARGE ADDITIONAL FEES

VIII.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges if extra claims are authorized.

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 C.F.R. § 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 C.F.R. § 1.26(a).

☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper and during the entire pendency of this application to Account No. 12-0425

☐ 37 C.F.R. § 1.492(a)(1), 1.492(a)(4) (filing fees)

☐ 37 C.F.R. § 1.492(b), (c), and (d) (presentation of extra claims)

NOTE: *Because additional fees for excess or multiple dependent claims not paid on filing or on later presentation must only be paid or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 C.F.R. § 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.*

☒ 37 C.F.R. § 1.17 (application processing fees)

☒ 37 C.F.R. § 1.17(a)(1)-(5)(extension fees pursuant to § 1.136(a)).

NOTE: *Section 1.311(b) provides that an authorization to charge the issue fee (§ 1.18) to a deposit account may be filed in an individual application **only after the mailing of the notice of allowance**. Accordingly, general authorizations to any fees and specific authorizations to pay the issue fee that are filed prior to the mailing of a notice of allowance will generally not be treated as requesting payment of the issue fee and will not be given effect to act as a reply to the notice of allowance. Applicant, when paying the issue fee, should submit a new authorization to charge fees, such as by completing box 6b on the current PTOL 85-B form. Where no reply to the notice of allowance is received, the application will stand abandoned notwithstanding the presence of general authorizations to pay fees or a specific authorization to pay the issue fee that were submitted prior to mailing of the notice of allowance. Where an attempt is made to pay the issue fee but an incorrect amount is submitted, § 1.311(b)(1), or where the Office's issue fee transmittal form (currently PTOL-85(B)) is completed by applicant and submitted, § 1.311(b)(2), in reply to a notice of allowance, an exception will be made. Such submissions will operate as a request to charge the issue fee to any deposit account identified in a previously filed (i.e., submitted prior to the mailing of the notice of allowance) authorization to charge fees, and will be allowed to act as payment of the correct issue fee. § 1.311(b). See also the change to § 1.26(b), Notice of September 8, 2000, Fed. Reg. 54603-54683, at 54646 and 54647.*

☐ 37 C.F.R. § 1.492(e) and/or (f) surcharge fees for filing the declaration and/or an English translation of an international application later than 30 months from the earliest-claimed priority date.

WARNING: *It would be wise to always check this last authorization.*

Refund any overpayment to deposit account 12-0425.

Reg. No.: 31053

Tel. No.: (212) 708-1915

Customer No.: 00140

SIGNATURE OF PRACTITIONER

JOHN RICHARDS

(type or print name of practitioner)

P.O. Address

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